The Honorable Lauren King 1 2 3 4 5 6 7 UNITED STATES DISTRICT COURT 8 WESTERN DISTRICT OF WASHINGTON AT SEATTLE 9 10 STATE OF WASHINGTON, et al. Case No. 2:25-cv-00244 11 [PROPOSED] BRIEF OF DO NO HARM, Plaintiffs, 12 INC. AS AMICUS CURIAE IN OPPOSITION TO PLAINTIFFS' MOTION v. 13 FOR A PRELIMINARY INJUNCTION DONALD J. TRUMP, in his official 14 capacity as President of the United States of America, et al., 15 16 Defendants. 17 18 19 20 21 22 23 24 25 26 27

Case 2:25-cv-00244-LK Document 219-1 Filed 02/25/25

Page 1 of 20

TABLE OF CONTENTS

2	<u>Page</u>			
3	CORPORATE DISCLOSURE STATEMENT			
4	INTRODUCTION & INTEREST OF AMICUS CURIAE			
5	ARGUMENT			
67	I. In The Practice Of Evidence-Based Medicine, Systematic Reviews Are The Highest Form Of Medical Evidence			
8	II. Every Systematic Review Of Medical and Surgical Interventions For Minors With Gender Dysphoria Has Concluded The Evidence Is Weak			
10	III. Plaintiffs Either Misunderstand Or Misrepresent The Principles Of Evidence-Based Medicine And Make Numerous Erroneous Assertions			
11	CONCLUSION			
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				

[PROPOSED] *AMICUS* BRIEF OF DO NO HARM, INC. IN OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION NO. 2:25-CV-00244 – 1

CORPORATE DISCLOSURE STATEMENT

Do No Harm, Inc., has no parent corporation, and no publicly held corporation holds any stock in Do No Harm, Inc.

[PROPOSED] *AMICUS* BRIEF OF DO NO HARM, INC. IN OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION NO. 2:25-CV-00244 – 2

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INTRODUCTION & INTEREST OF AMICUS CURIAE

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"Gender affirming care" is a medical scandal. This purported "treatment" calls for a host of biology-denying medical interventions from puberty blockers to cross-sex hormones to genital surgeries. All this to treat a *psychological* condition. These interventions inflict grave harms, and there is no reliable evidence demonstrating that they improve, much less resolve, gender dysphoria.

Do No Harm, Inc., ¹ is a nonprofit membership organization that includes over 16,000 physicians, nurses, medical students, patients, and policymakers. Do No Harm is committed to ensuring that the practice of medicine is driven by scientific evidence rather than ideology. In recent years, the practice of biology-denying interventions, euphemistically known as "gender affirming care," has become more common despite the serious harm caused by those medical interventions and the complete lack of reliable evidence for any benefit caused by them. Indeed, Do No Harm has recently released a database demonstrating that nearly 14,000 minors were subjected to biology-denying interventions in the United States between 2019 and 2023. *See Do No Harm Launches First National Database Exposing the Child Trans Industry*, Do No Harm (Oct. 8, 2024), https://bit.ly/4f2AJPt.

Part of Do No Harm's mission is to ensure that courts have a proper understanding of the dangers of these medical interventions and the lack of evidence supporting them. To that end, Do No Harm submits this brief to provide the Court with an accurate analysis of the lack of evidence justifying the use of puberty blockers, cross-sex hormones, and surgeries as

¹ No party's counsel authored, in whole or in part, this brief; and no person other than *amicus curiae*, its members, or its counsel contributed money that was intended to fund preparing or submitting this brief. *Cf.* Fed. R. App. P. 29(a)(4)(E)

treatments for gender dysphoria. Specifically, the President's executive order, *Protecting Children from Chemical and Surgical Mutilation*, is justified by the known harms of these interventions—including the sterilization of healthy boys and girls—and the complete lack of evidence showing that they do anything to resolve gender dysphoria.

The lack of evidence of benefit from these interventions has been established in every systematic review to analyze the question. These reviews—which represent the highest form of medical evidence—have been conducted by health authorities in Finland, Sweden, the U.K., and by expert researchers hired by the health authority in the State of Florida and the U.K.'s National Health Service. All of them have concluded that no reliable evidence demonstrates that these interventions help resolve gender dysphoria.

The Plaintiffs largely ignore not only these systematic reviews, but also the basic principles of evidence-based medicine. Instead, they rely on either doctors' clinical experience (the *lowest* form of medical evidence) or on individual studies that are unreliable due to their high risk of scientific bias (as found in the systematic reviews described above). In addition, Plaintiffs resort to conflating biology-denying interventions with the treatment for conditions that carry *vastly* different risks and benefits. This too ignores principles of not only evidence-based medicine, but also common sense.

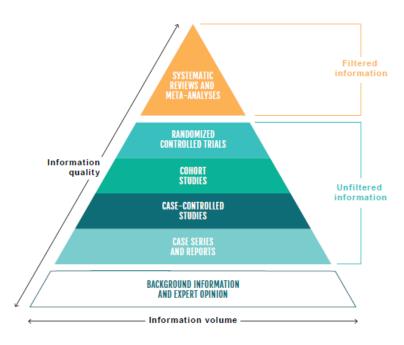
Most significantly, despite the State's grossly irresponsible assertion that, "if the [Executive] Orders stand, transgender children will die," Pls'. Prelim. Inj. Mot. at 1, Dkt. 169 (Feb. 19, 2025) ("PI Mot."), there is no reliable evidence whatsoever that biology-denying interventions reduce the risk of suicide. Indeed, the very experts that the State is relying on here have *affirmatively disavowed* the idea that there is any indication that these interventions reduce suicide. Based on the medical evidence, the President is wholly justified in taking

actions to limit the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria in minors.

ARGUMENT

I. In The Practice Of Evidence-Based Medicine, Systematic Reviews Are The Highest Form Of Medical Evidence.

Although the proper practice of medicine is driven by evidence, not all medical evidence is created equal. Researchers have thus spent decades refining the process that clinicians use to assess the medical evidence supporting a particular medical intervention. That process—often referred to as the practice of "evidence-based medicine"—outlines a hierarchy of medical evidence based on the confidence a clinician can place in a particular source of evidence. *See* GORDON GUYATT, ET AL., USERS' GUIDES TO THE MEDICAL LITERATURE: ESSENTIALS OF EVIDENCE-BASED CLINICAL PRACTICE 15 fig. 2-3, JAMAEVIDENCE (3d ed. 2015) ("Evidence-Based Medicine User Guide"). The "pyramid of standards of evidence" reflects the hierarchy of reliability for evidence in medicine:



See Independent Review of Gender Identity Services for Children and Young People: Final Report, NAT'L HEALTH SERV. ENG. 55 (Apr. 2024) ("Cass Review"). As the pyramid shows, "systematic reviews" are at the top of the hierarchy of medical evidence. At the bottom of the hierarchy is clinical experience—*i.e.*, "the unsystematic observations of individual clinicians." Evidence-Based Medicine User Guide at 15.

Systematic reviews provide the greatest insight into the medical evidence underpinning a particular intervention because they account for all relevant studies, assess those individual studies for areas of potential scientific bias, and thus show the *reliability* of the *entire* evidence base. *See id.* at 274-76. To assess bias in individual studies, Researchers frequently use tools such as the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method. *See id.* at 16-17. In the GRADE system, researchers rate the evidence using specified criteria. "In the context of a systematic review, the ratings of the quality of evidence reflect the extent of our confidence that the estimates of the effect are correct." Howard Balshem, et al., *GRADE Guidelines: 3. Rating the Quality of Evidence*, 64 J. CLINICAL EPIDEMIOLOGY 401, 403 (2011). This resulting rating of the evidence is either "high, moderate, low, or very low." Evidence-Based Medicine Users Guide at 16. The following definitions explain what the various levels mean:

<u>High Quality Evidence</u>: "We are *very confident* that the true effect lies close to that of the estimate of the effect." Balshem, *supra*, at 404 tbl. 2 (emphasis added).

Moderate Quality Evidence: "We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different." *Id.* (emphasis added).

<u>Low Quality Evidence</u>: "Our *confidence* in the effect estimate *is limited*: The true effect may be *substantially different* from the estimate of the effect." *Id.* (emphasis added).

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<u>Very Low Quality Evidence</u>: "We have *very little confidence* in the effect estimate: The true effect *is likely to be substantially different* from the estimate of effect." *Id.* (emphasis added).

Thus, when evidence is deemed "low" or "very low" quality, that means researchers have "limited" or "very little confidence" that the results of the study reflect the truth; indeed, the truth may or *likely* will turn out "to be substantially different" from what such studies say.

Finally, after analyzing all relevant studies, the researchers will "summarize the results." Evidence-Based Medicine User Guide at 275. This process can include a quantitative synthesis or "meta-analysis" of data that provides an overview to clinicians. *See id.* at 275-76. The end result is a study of studies—a comprehensive look at the evidence on a given question that accounts for the reliability of the studies forming the evidence base.

In sum, systematic reviews are the most reliable form of medical evidence. And for several reasons, they are substantially more reliable than narrative reviews (such as a clinician's experiences recounted in a declaration or expert-witness report). First, unlike systematic reviews, narrative reviews "have no explicit criteria for selecting the included studies." *Id.* at 273. Therefore, narrative reviews can cherry-pick examples and individual studies—discussing only those that support their conclusions and ignoring those that do not. Systematic reviews do not suffer from this flaw.

Second, narrative reviews "do not include systematic assessments of the risk of bias associated with primary studies." *Id.* (emphasis omitted). Thus, narrative reviews may stress that several studies all support the same conclusion, but "[c]onsistent results are less compelling if they come from studies with a high risk of bias than if they come from studies with a low risk of bias." *Id.* at 283. Systematic reviews account for this principle; narrative reviews do not. For these reasons (among others), systematic reviews represent the highest

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form of medical evidence, and "optimally effective evidence-based practice dictates bypassing the critical assessment of primary studies and, if they are available, moving straight to the evaluation of rigorous systematic reviews." *Id.* at 4 (emphasis omitted).

II. Every Systematic Review Of Medical And Surgical Interventions For Minors With Gender Dysphoria Has Concluded The Evidence Is Weak.

Several entities and institutions have conducted systematic reviews to assess the evidence underlying the use of puberty blockers and cross-sex hormones as a treatment for minors with gender dysphoria. All have concluded that the evidence underlying medical interventions for gender dysphoria in minors is weak; zero have come out the other way.

<u>Finland</u>. The first systematic review came in 2019 when Finland's Ministry of Social Affairs and Health completed its review of the medical evidence. In light of this evidence review, Finland's healthcare authority concluded that "gender reassignment of minors is an experimental practice." This conclusion was based on the fact that "[t]he reliability of the existing studies" is "highly uncertain."

The Cass Review Interim Report. Next, in 2020, the United Kingdom's National Institute for Health and Care Excellence (NICE) completed its review of the evidence for using puberty blockers and cross-sex hormones on minors with gender dysphoria to aid the Cass Review, an independent review commissioned by the United Kingdom's National Health Service. The result was two separate systematic reviews—one for puberty blockers and one

² See Recommendation of the Council for Choices in Health Care in Finland (PALKO/COHERE Finland): Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors at 8, PALVELUVALIKOIMA (Nov. 6, 2020) (unofficial translation by the Society for Evidence Based Gender Medicine (SEGM)), https://perma.cc/PF72-H654.

³ *Id*. at 7.

⁴ See NICE Evidence Reviews, THE CASS REV., https://perma.cc/APZ2-W8MS (last visited Feb. 24, 2025).

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for cross-sex hormones.⁵ The review of puberty blockers concluded that the relevant studies were "all small, uncontrolled observational studies, which are subject to bias and confounding, and all the results are of very low certainty using [a] modified GRADE" methodology.⁶ Similarly, in the review of cross-sex hormones, NICE concluded that the relevant studies were "uncontrolled observational studies, which are subject to bias and confounding and were of very low certainty using [a] modified GRADE" methodology.⁷

The State of Florida. In 2022, researchers at Canada's McMaster University—a world-renowned institution in evidence-based medicine—completed a systematic review at the request of the Florida Agency for Health Care Administration. See Romina Brignardello-Petersen & Wojtek Wiercioch, Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence 5 (May 16, 2022), https://perma.cc/S4A3-NKDY. They too found that the evidence supporting these interventions was weak. "Due to the important limitations in the body of evidence," they concluded, "there is great uncertainty about the effects of puberty blockers, cross-sex hormones, and surgeries in young people with gender dysphoria." Id.

Sweden. In 2023, Swedish researchers published a systematic review that was commissioned by Sweden's Agency for Health Technology and Assessment of Social Services. See Jonas F. Ludvigsson, et al., A Systematic Review of Hormone Treatment for Children with

⁵ Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria, NAT'L INST. FOR HEALTH & CARE EXCELLENCE (Oct. 2020), https://perma.cc/F9FF-ZPFR ("NICE – Review of Puberty Blockers"); Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria, NAT'L INST. FOR HEALTH & CARE EXCELLENCE (Oct. 2020), https://perma.cc/U49T-JLGJ ("NICE – Review of Cross-Sex Hormones").

⁶ NICE – Review of Puberty Blockers at 13.

⁷ NICE – Review of Cross-Sex Hormones at 13.

Gender Dysphoria and Recommendations for Research, 112 ACTA PAEDIATRICA 2279 (2023), https://perma.cc/E7S9-7CLB. The review concluded that the "[e]vidence to assess the effects of hormone treatment" on (among other things) mental health in minors "with gender dysphoria is insufficient." *Id.* at 2280. Specifically, it noted that "[l]ong-term effects of hormone therapy on psychosocial health are unknown," and using puberty blockers to treat gender dysphoria "should be considered experimental treatment." *See id.*

The Cass Review Final Report. Most recently, researchers from York University published a series of systematic reviews as part of the Cass Review. The York University researchers conducted systematic reviews of the evidence for both puberty blockers and cross-sex hormones. In their review of puberty blockers, the researchers concluded that their "findings add to other systematic reviews in concluding there is insufficient and/or inconsistent evidence about the effects of puberty suppression on gender dysphoria, body satisfaction, psychological and psychosocial health, cognitive development, cardiometabolic risk and fertility." Similarly, in their review for cross-sex hormones, the researchers concluded that their "findings add to other systematic reviews in concluding there is insufficient and/or inconsistent evidence about the risks and benefits of hormone interventions in this population." 10

⁸ See Jo Taylor et al., Interventions To Suppress Puberty in Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review, ARCHIVES DISEASE CHILDHOOD 1 (2024), https://bit.ly/402E7WC ("Taylor – Puberty Blockers"); Jo Taylor et al., Masculinising and Feminising Hormone Interventions for Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review, ARCHIVES DISEASE CHILDHOOD 1 (2024), https://bit.ly/4dE9Pws ("Taylor – Cross-Sex Hormones").

⁹ Taylor – Puberty Blockers at 12.

¹⁰ Taylor – Cross-Sex Hormones at 6.

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In sum, all these systematic reviews concluded the same thing: there is no reliable evidence to justify the use of puberty blockers and cross-sex hormones as a treatment for gender dysphoria in minors. And this conclusion comports with the findings of the experts in evidence-based medicine hired by the organization WPATH (which Plaintiffs invoke at PI Mot. at 2), a research team at Johns Hopkins University, who reported that they "found 'little to no evidence about children and adolescents'" for these interventions.¹¹

III. Plaintiffs Either Misunderstand Or Misrepresent The Principles Of Evidence-Based Medicine And Make Numerous Erroneous Assertions.

Plaintiffs ignore the systematic reviews described above because Plaintiffs have no answer to them. Instead, Plaintiffs attempt to conflate biology-denying interventions with the use of puberty blockers and surgical procedures to treat *other* conditions. But those other treatments carry risks and benefits that *vastly* differ from the interventions at issue here. And Plaintiffs' attempt to conflate them is meritless.

To aid the Court, *amicus* provides a selection of Plaintiffs' most egregious assertions followed by an explanation of why those assertions are plainly wrong.

1. "Simply put, if the Orders stand, transgender children will die." PI Mot. at 1. This outrageous rhetoric is grossly irresponsible, supported by no data, and outright contradicted by Plaintiffs' own experts. To start, even a researcher for WPATH admits this is wrong: "There is insufficient evidence to draw a conclusion about the effect of hormone therapy on death by suicide among transgender people." Kellan E. Baker, et al., Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review, 5 J. ENDOCRINE SOC'Y

¹¹ See Trans Health Group Fought Study Analyzing 'Gender Affirming Care' for Children, Docs Show, Do No Harm (May 17, 2024), https://bit.ly/41yv1RS (citation omitted).

1, 13 tbl. 6 (2021), https://perma.cc/6D6Q-GDQA; see also id. at 12 ("It was impossible to draw conclusions about the effects of hormone therapy on death by suicide."). And just last year, in what is likely the most controlled environment that is currently feasible, a researcher in the U.K. concluded that there was no evidence of a rise in suicides after the country's health service had restricted the use of puberty blockers as a treatment for gender dysphoria. See Puberty Blocker Curb Has Not Led to Suicide Rise—Review, BBC (July 20, 2024), https://perma.cc/J36J-HWLN.

Most alarmingly, just months ago, Plaintiffs' leading experts, Drs. Shumer and Antommaria, (*see* Decl. of Dr. Antommaria, Dkt. 18 (Feb. 7, 2025); Decl. of Dr. Shumer, Dkt. 19 (Feb. 7, 2025)), said precisely the opposite of what Plaintiffs say in their brief. Specifically, Plaintiffs repeatedly invoke the risk of suicide as a harm resulting from the executive orders. *See* PI Mot. at 1-2, 21, 23. But in litigation over a law restricting the practice of these very same interventions, Plaintiffs' expert Dr. Shumer had the following to say:

Q. And you agree there is no data linking gender-affirming care to a reduction in suicide, correct?

...

A. Yes, I don't believe that there is strong data linking gender-affirming care in youth to an outcome of less completed suicides.

Dep. Tr. of Dr. Shumer at 157:4-10, *Misanin v. Wilson*, No. 2:24-cv-4734-RMG (Oct. 31, 2024), Dkt. 46-3 ("Shumer *Misanin* Tr."). Dr. Antommaria echoed the same sentiment that there is no data linking these interventions to a reduction in suicide:

Q. Can you name any study demonstrating that medical transition for adolescents reduces the rate of completed suicides among any population of transgender adolescents?

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[PROPOSED] AMICUS BRIEF OF DO NO HARM, INC. IN OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

NO. 2:25-CV-00244 - 13

A. No, sir. I'm not aware of such a study.

See Dep. Tr. of Dr. Antommaria at 131:15-21, *Misanin v. Wilson*, No. 2:24-cv-4734-RMG (Oct. 31, 2024), Dkt. 46-4 ("Antommaria *Misanin* Tr."). Plaintiffs' threat to this Court—that "transgender children will die"—absent a preliminary injunction is shocking given the actual data on this question. PI Mot. at 1.

2. "[N]on-surgical treatments . . . are generally the only treatments minors can receive." PI Mot. at 19. This assertion is, again, completely divorced from the data. As mentioned above, Do No Harm has created a database that catalogs the gender-transition interventions performed on minors throughout the United States. See About the Project, Do No Harm, https://bit.ly/3Xf6Mp0 (last visited Feb. 24, 2025). According to this data, between 2019 and 2023, nearly 5,750 minors were operated on as part of their treatment for gender dysphoria. Id. Indeed, in the Plaintiff States, surgeries were performed on almost a thousand minors:

- Oregon: 357 minors received surgery as a treatment for gender dysphoria 12
- Washington: 330 minors received surgery as a treatment for gender dysphoria¹³
- Minnesota: 174 minors received surgery as a treatment for gender dysphoria 14

¹² State Breakdown: Oregon, Stop The Harm Database, Do No HARM, available at https://bit.ly/3XfLRT0 (last visited Feb. 24, 2025).

¹³ State Breakdown: Washington, Stop The Harm Database, Do No HARM, available at https://bit.ly/41un13Z (last visited Feb. 24, 2025).

¹⁴ State Breakdown: Minnesota, Stop The Harm Database, Do No HARM, available at https://bit.ly/41f5g7z (last visited Feb. 24, 2025).

• Colorado: 60 minors received surgery as a treatment for gender dysphoria 15
In light of these facts, it is difficult to understand how Plaintiffs can represent to the Court that "non-surgical treatments" are generally the "only treatments minors can receive." PI Mot. at 19.

3. "The quality of evidence supporting this care is comparable to the quality of evidence supporting countless other medical treatments provided to minors." Id. at 11. In support of this assertion, Plaintiffs cite several paragraphs from Dr. Antommaria's expert declaration where he states that recommendations for many interventions are made based on "low" or "very low" quality evidence under the GRADE methodology. See Antommaria Decl. ¶¶ 44-47. In particular, he compares the use of puberty blockers to treat central precocious puberty to the use of puberty blockers to treat gender dysphoria.

But the risks and benefits associated with different interventions for different conditions should not be conflated. See Evidence-Based Medicine User Guide at 6 (noting that providers must determine "the tradeoff among the benefits, risks, and burdens of alternative management strategies" (emphasis omitted)). It is common sense that uncertainty about the benefit of a drug is less significant when the risks associated with taking that drug are low. For example, if there is low risk in brushing one's teeth with fluoride, then one need not be concerned if there is low quality evidence of the benefit of brushing with fluoride toothpaste. Relatedly, uncertainty about the benefit of a drug is less significant when the marginal risk associated with taking that drug is low. For example, if there is little marginal risk in

¹⁵ State Breakdown: Colorado, Stop The Harm Database, Do No HARM, available at https://bit.ly/3DiFBTo (last visited Feb. 24, 2025).

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prescribing an experimental drug to a patient suffering from an aggressive form of lifethreatening cancer, then uncertainty about the benefit is less concerning. This principle—close to a "nothing-to-lose" situation—is reflected in the lone situation where the GRADE methodology permits a strong recommendation in favor of an intervention supported by lowquality evidence. See Ming C. Chong, et al., Strong Recommendations from Low Certainty Evidence: A Cross-Sectional Analysis of a Suite of National Guidelines, 23 BMC MED. RSCH. METHODOLOGY 1, 3 tbl. 1 (2023), https://perma.cc/A6JB-VUS5. The upshot is that using interventions to treat different conditions carries different risks and benefits that must be analyzed separately.

Plaintiffs ignore this fundamental principle in two ways. First, they imply that, because some medical treatments are provided based on low-quality evidence, then providers should be permitted to offer biology-denying interventions based on low-quality evidence. See, e.g., PI Mot. at 11 (noting "comparable" evidence quality to other treatments). Second, Plaintiffs contend that, because providers offer puberty blockers to treat central precocious puberty or surgery to treat gynecomastia in boys, then providers should be permitted to offer puberty blockers or mastectomies to treat gender dysphoria. See, e.g., id. at 10 (gynecomastia); id. at 11 (precocious puberty).

The critical flaw in this argument is that there are no interventions—including the ones Plaintiffs highlight—that share a similar risk-benefit profile with the interventions at issue in this case. Take central precocious puberty for example. That treatment involves delaying puberty until the normal age, at which point the boy or girl will proceed through his or her

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natural puberty. With biology-denying interventions, however, the patient's natural puberty is permanently suppressed by administering puberty blockers at later ages. The harms and risks of *never* going through natural puberty are vastly different from merely delaying one's natural puberty until the normal age. For example, unlike a child who takes puberty blockers to treat central precocious puberty, a gender dysphoric child whose puberty is suppressed and then continues on cross-sex hormones will be sterilized—as Plaintiffs' own experts have admitted elsewhere. *See* Antommaria *Misanin* Tr. 49:5-11 (admitting that a patient who proceeds from pubertal suppression to cross-sex hormones "would be anticipated to be infertile").

The same is true of Plaintiffs' other leading example of gynecomastia. In rare circumstances, that treatment can call for the surgical removal of chest tissue in a boy. ¹⁷ But removing chest tissue from a boy to treat gynecomastia is not the same as performing a mastectomy on an adolescent girl to treat a *psychological disorder*. Performing a mastectomy on an adolescent girl means that she will likely never have the ability to breastfeed a child; ¹⁸ it should go without saying, but a boy does not have the ability to breastfeed a child anyway. Thus, the harms of these procedures are *vastly* different.

In sum, the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria carries a *host* of known harms and risks and has no reliable evidence of benefit. The treatments that Plaintiffs attempt to analogize to biology-denying interventions at issue here

¹⁶ Precocious Puberty, MAYO CLINIC, https://perma.cc/4FL2-9PL5 (last visited Feb. 24, 2025) (noting that treatment may involve children receiving GnRH analogues "until they reach the usual age of puberty," at which point "the treatment stops" and "puberty starts again").

¹⁷ Ruth E. Johnson & M. Hassan Murad, *Gynecomastia: Pathophysiology, Evaluation, and Management*, 84 MAYO CLINIC PROC. 1010, 1012 (2009), https://perma.cc/5898-8HJU.

¹⁸ See, e.g., Karleen D. Gribble et al., Breastfeeding Grief After Chest Masculinisation Mastectomy and Detransition: A Case Report with Lessons About Unanticipated Harm, FRONTIERS IN GLOB. WOMEN'S HEALTH 2 (2023), https://perma.cc/ZMY7-VP9T.

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have no comparable risk-benefit profile. For example, permitting the treatment of central precocious puberty is no argument for permitting providers to sterilize a boy or girl through puberty blockers and cross-sex hormones. The United States is entirely justified in taking actions to limit the use of these dangerous and unproven interventions.

* * *

Finally, *amicus* will highlight for the Court the numerous critical aspects of both gender dysphoria and these interventions that are wholly unknown—as demonstrated by the following admissions from *Plaintiffs' own experts* in litigation over these same issues:

- We do not know what causes gender dysphoria. Shumer *Misanin* Tr. 33:18-21.
- We cannot determine whether any particular individual with gender dysphoria will continue to be transgender in the future. *Id.* at 33:22-25.
- We have no idea what the long-term effects of pubertal suppression are on neurodevelopment. Antommaria *Misanin* Tr. 47:3-12.
- We do not understand why there has been a sudden and recent increase in the number of individuals with gender dysphoria. *Id.* at 30:9-31:7.
- We do not know why this increase has disproportionately affected females. *Id.* at 31:9-32:4.
- We do not know why there is an overrepresentation of individuals with an Autism Spectrum Disorder. *Id.* at 42:7-17; Shumer *Misanin* Tr. 27:20-28:2.
- We do not know if patients' bone mineral density will ever return to normal later in life after taking puberty blockers. Antommaria *Misanin* Tr. 45:17-46:7.
- We have no data regarding patient outcomes after the age of 30 for adolescents who used puberty blockers followed by cross-sex hormones. *Id.* at 53:6-12 ("I'm not aware of any studies" that follow "individuals to their 30th birthday when measuring the safety or efficacy of puberty blockers followed by cross-sex hormones[.]").

CONCLUSION

The Court should deny Plaintiffs' motion for a preliminary injunction.

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1	Respectfully submitted, this 25th d	lay of February, 2025.
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	[PROPOSED] AMICUS BRIEF OF	Ellis Li McKinstry

[PROPOSED] *AMICUS* BRIEF OF DO NO HARM, INC. IN OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION NO. 2:25-CV-00244 – 18

CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of February 2025, I electronically filed the foregoing document with the Clerk of the United States District Court using the CM/ECF system, which will send notification of such filing to all parties who are registered with the CM/ECF system.

DATED this 25th day of February 2025.

/s/ Keith Kemper Keith Kemper